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In re Application of :
YOSHIMURA ET AL. :Decision on Petition
Serial No.: 10/507,385 :
Filed : September 9, 2004 :
Attorney Docket No.: 4239-64104-02 :

This letter is in response to the Petition under 37 C.F.R. 1.144 filed on May 15, 2008 requesting review of a lack of unity determination. The delay in acting upon this petition is regretted.

BACKGROUND

This application was filed as a national stage application under 35 USC 371 of PCT/US02/39793 and as such, is eligible for unity of invention practice.

In a written lack of unity determination mailed January 3, 2007, the examiner divided claims 1-45 into seven groups and then requested that applicants select particular species depending on which group was selected. The originally filed claims were misnumbered, as they were missing Claims 34-36. The preliminary amendment renumbered the claims such that there were only Claims 1-42. The examiner provided a prior art reference to support this determination for lack of unity.

On February 5, 2007, applicants elected Group III, claims 11-22, and granulocyte-macrophage-colony stimulating factor, constitutive promoter and CD40 ligand with traverse.

In the first Office action of the merits mailed April 19, 2007, the examiner considered the traversal and made the unity of invention determination FINAL.

Claims 11-22 were examined. Claims 11-16, 21-22 were rejected under 35 USC 102(a) for being anticipated by Kamohara et al. Claims 11-20 were rejected under 35 USC 103(a) as being obvious over Kamohara in view of Lipford.

A response to the Office action was filed on September 19, 2007 where applicants submitted an unsigned statement under 37 C.F.R. 1.497 Regarding Inventorship, consent of Assignee under 37 C.F.R. 1.497, a declaration under 1.132 signed by Yoshimura and an unsigned new Declaration by Dr. Kamohara.

Applicants filed a supplemental response on September 28, 2007 including a signed 1.132 by Dr. Kamohara and a new Declaration by Dr. Kamohara.

On November 29, 2007, the Examiner mailed a non-compliant amendment notice.

On December 28, 2007, Applicant filed a complete listing of the pending claims, as required by the Examiner. This listing of Claims, however added new Claims beginning with Claim 46, rather than beginning with Claim 43. The amendment noted that Claims 43-45 were cancelled, however Claims 43-45 were never pending.

On March 20, 2008 the Examiner mailed a FINAL Office action.

On May 15, 2008, Applicant filed this petition requesting reconsideration under 37 C.F.R 1.144 of the lack of unity requirement.

A Request for Continued Examination was filed on August 20, 2008 along with a Rule 1.48 Request to correct inventorship.

DISCUSSION

Applicants' petition filed May 15, 2008 and the file history have been considered carefully. The petition argues that the unity of invention determination was incorrect because there is a special technical feature which is a contribution over the art.

As provided in the PCT International search and preliminary examination guidelines, paragraph 10.03 provides that Lack of unity of invention may be directly evident "*a priori*," that is, before considering the claims in relation to any prior art, or may only become apparent "*a posteriori*," that is, after taking the prior art into consideration. For example, independent claims to A + X, A + Y, X + Y can be said to lack unity *a priori* as there is no subject matter common to all claims. In the case of independent claims to A + X and A + Y, unity of invention is present *a priori* as A is common to both claims. However, if it can be established that A is known, there is lack of unity *a posteriori*, since A (be it a single feature or a group of features) is not a technical feature that defines a contribution over the prior art.

Moreover, the PCT International Search and Preliminary Examination Guidelines, published January 2004 provide Example 38 that addresses unity of invention with regard to a method of screening. This example is reproduced below for convenience.

Example 38: Method of Screening and Compounds Identified by the Method

Claim 1: A method to identify compounds that are antagonists of receptor R comprising the steps of contacting cells expressing on their outer membrane receptor R with its natural ligand; observing the binding of the ligand; contacting said cells bound to said ligand with a candidate compound selected from a library of compounds; and observing any change in the binding of the ligand.

Claim 2: Compound X, having formula 1.
Claim 3: Compound Y, having formula 2.
Claim 4: Compound Z, having formula 3.

Receptor R and its natural ligand are proposed as a drug target. Compounds that antagonise receptor R are proposed to have physiological effects that may be useful in therapeutic treatment. The aim is to identify lead compounds as a basis for further screening and testing of combinatorial libraries. A library is described as providing many possible structurally different compounds. Examples show that the method of claim 1 can be used to identify compounds affecting the physiological effect of binding of the natural ligand to the receptor. Only compounds X, Y and Z were shown to have such effects, but they do not appear to share a significant structural element. The description is silent with regard to the both the relationship between the structure and activity of the claimed compounds and the relationship between the structure of receptor R and the structure of the compounds.

Receptor R, its biological function, and its natural ligand are known in the prior art. No compounds that function as antagonists of receptor R are known.

The technical feature of method claim 1 resides in the step of observing the effect of the candidate compounds on ligand binding in a screening assay. Neither the same nor a corresponding special technical feature is present in any of compounds X, Y, or Z. No manufacturing relationship exists between the screening method and the claimed compounds.

Further, the screening method is not a method of using claimed compounds X, Y, and Z. In the absence of any teaching as to the structure required for a compound to act as a receptor R antagonist, there is no single general concept that links the method to the claimed compounds. Thus, unity of invention is lacking (*a priori*).(emphasis added by underlines)

Compounds X, Y, and Z would be regarded as having the same or corresponding technical feature if they had a common property or activity, and shared a significant structural element that is essential to the common property or activity. While compounds X, Y, and Z do share the common property of antagonising receptor R, there is no teaching as to a shared significant structural element, and hence, there is no disclosure of the same or corresponding technical feature.

One possible grouping would be:

Invention 1: Method to identify compounds... (claim 1)
Invention 2: Compound X (claim 2)
Invention 3: Compound Y (claim 3)
Invention 4: Compound Z (claim 4)

In contrast to ISPE Guidelines Example 38, in the instant application, only method claims are presented; there are no claims directed to any products. Determination of unity of invention among method claims generally involves analysis of the active steps required by the methods. In the instant application, the methods of Group I and II do not share a special technical feature with elected Group III for the following reasons. Group III requires the active step of inducing maturation of the immature macrophage or immature dendritic cell whereas Groups I and II do not require any active step of induction. Screening methods, such as Groups I and II are commonly used to both identify compounds with the desired activity, as well as identify compounds which lack the desired activity. Groups I and II in fact are directed to determining whether there is any specific binding to the DDR1. This active step is not required in Group III. For Groups I and II when the screening method is preformed using a candidate compound that is not a DDR1 agent, no induction occurs. Moreover, Group III requires the active step of activating DDR1, which is not required for Groups I or II. Thus, there is no special technical feature to link Groups (I and II) with Group III.

Group V, Claims 26-30, requires administering an agent that specifically binds to DDR1b. This technical feature is not required by any of the other groups.

Group VII, Claims 48-50, requires a different special technical feature not required by the other Groups. Group VII requires contacting a leukocyte with an antibody that specifically binds to DDR1a which is not required by any of the other groups.

For these reasons, Groups I, II, V and VII lack unity of invention with elected Group III.

Turing now to the consideration of unity of invention between Groups III and VI, representative claims from each group are set forth below:

Claim 11, from elected Group III

11. (Previously presented) A method of inducing maturation of an immature macrophage or an immature dendritic cell that expresses Discoidin Domain Receptor 1 (DDR1), comprising:

contacting the immature macrophage or the immature dendritic cell with an effective amount of a DDR1-activating agent, thereby inducing maturation of the immature macrophage or the immature dendritic cell that expresses DDR1.

Claim 31 from non-elected Group VI

31. (Withdrawn) A method of activating a neutrophil or a lymphocyte, comprising

activating a Discoidin Domain Receptor 1 (DDR1) signalling pathway in the neutrophil or the lymphocyte, thereby activating the neutrophil or the lymphocyte.

A comparison of Claim 11 and 31 shows that Group VI lacks technical feature with elected Group III. Group VI, Claims 31-33, 46-47, are drawn to activating a DDR1 pathway in the neutrophil or lymphocyte, thereby activating the neturophil or lymphocyte. This feature is not required by Group III. Claim 31 is a method of activating a neturophil or a lymphocyte (B or T cells); this feature is not required by Group VI. Thus, Group III and Group VI lack unity of invention, a priori.

Claim 23, from non-elected Group IV is set forth below:

23. (Withdrawn) A method for producing an antigen presenting macrophage or dendritic cell, comprising

contacting an immature monocyte or an immature dendritic cell with an agent that activates Discoidin Domain Receptor 1 (DDR1) in the presence of an antigen,

thereby producing an antigen presenting mature dendritic cell or an antigen presenting macrophage.

Claim 11 of Group III and Claim 23 of Group IV require contacting the immature macrophage or immature dendritic cell with an effective amount of a DDR1 activating agent to induce maturation of the immature macrophage or the immature dendritic cell that expresses DDR1 or to produce an antigen presenting mature dendritic cell or antigen presenting macrophage. While claim 11 and 23 are worded differently, the technical features required the claims are similar. The specification discloses that "activation of DDR1 by a DDR1-activating agent induces the maturation of a dendritic cell precursor, for example, a monocyte into a macrophage or a dendritic cell. Contacting a dendritic cell precursor with an effective amount of an antigen, in addition to an effective amount of a DDR1-activatign agent, can induce the maturation of the dendritic cell precursor into an antigen –presenting dendritic cell." (pages 2-3, bridging paragraph.) For these reasons, Group IV, Claims 23-25, have unity of invention with originally examined Group III, Claims 11-22 and newly added 55-57.

Further more, 37 CFR 1.475(b) provides guidance concerning various categories of invention permitted for national stage filings under 35 USC 371.

> 1.475 Unity of invention before the International Searching Authority, the International Preliminary Examining Authority and during the national stage
>
> (b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or
(2) A product and process of use of said product; or
(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
(4) A process and an apparatus or means specifically designed for carrying out the said process; or
(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

In this case, the method of screening for an agent and a method of using the agent do not appear to be within any of the combinations of categories listed above, thus a lack of unity of invention is permitted.

DECISION

Accordingly, the petition filed under 37 CFR 1.144 is **GRANTED-IN-PART**.

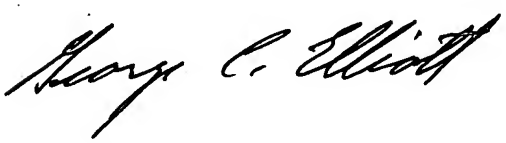
The restriction requirement is maintained between elected Group III and non-elected Groups I, II, V, VI and VII.

The restriction requirement is withdrawn between elected Group III and Group IV. Groups IV (Claims 23-25) have been rejoined with previously examined Group III (Claims 11-22 and newly added Claims 55-57).

The application will be forwarded to the examiner to consider the request for continued examination filed August 20, 2008, amendment, and Rule 1.48 request to correct inventorship and to prepare an Office action consistent with this petition decision.

Any request for reconsideration must be filed within two (2) months of the mailing date of this decision.

Should there be any questions regarding this decision, please contact Special Program Examiner Julie Burke, by mail addressed to Director, Technology Center 1600, PO BOX 1450, ALEXANDRIA, VA 22313-1450, or by telephone at (571) 272-1600 or by Official Fax at 703-272-8300.



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